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10/526,768	11/07/2005	Enno Klussmann	Gulde-0058	6937

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EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	**PAPER NUMBER**
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,768	KLUSSMANN ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008 and 06 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *6-8 and 11-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9,10 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *March 3, 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's responses on May 6 and June 6, 2008, to the First Action on the Merits of this case mailed November 6, 2007, are acknowledged. It is acknowledged that applicants have amended Claims 1, 2, 9, and 10 and added Claims 18-20. Claims 1-20 are pending. Claims 6-8 and 11-17 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-5, 9, 10, and 18-20 are hereby considered.

Sequence Listing

It is acknowledged that a new sequence listing has been filed. However, the new sequence listing continues to annotate SEQ ID NO: 1 as a human protein, while GenEMBL annotates SEQ ID NO: 1 as a rat protein (Accession no. AY350741/GI:37993505). Clarification is required.

Information Disclosure Statement

It is acknowledged that Applicants have filed reference #001 by Klussmann et al, 2000 listed on the prior IDS. Said reference has been considered. If Applicants wish for an IDS to be signed by the Examiner, it should be filed.

Drawings

Objection to the drawings because Figure 1 fails to identify the protein therein by a sequence identifier number (SEQ ID NO:) is maintained. Disclosure of the sequence in the sequence listing is not sufficient to overcome this objection.

Abstract

Objection to the abstract because it is a single, run-on sentence is maintained.

Specification-Objections

Objection to the specification for having an incomplete and improper listing of the figure legends, for the reasons explained in the prior action, is maintained.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of Claims 4, 5, 9, and 10 under 35 U.S.C. 112, second paragraph, as being indefinite because in each claim "a nucleic acid molecule according to Claim…" should be amended to "the nucleic acid molecule according to Claim…", is maintained.

Claims 1-5, 9, 10, and 18-20 are herein rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 1, line 16, the phrase "behavior which is analogous" renders the claim indefinite. It is unclear whether said phrase means enzymatic activity behavior, immunogenic activity behavior, anchoring activity behavior, 3-demensional structural behavior, some other behavior, or all behaviors of the AKAP18δ of SEQ ID NO: 2, including behaviors unknown at the time of filing. The skilled artisan would not know the metes and bounds of the recited invention. Claims 2-5, 9, 10, and 18-20, as dependent from Claim 1, are indefinite for the same reason. For purposes of examination, it is assumed that "behavior which is analogous" means the kinase activity of the AKAP18δ of SEQ ID NO: 2.

For Claim 2, line 2, and Claim 19, lines 3, the term "having" renders the claims indefinite. It is unclear whether said term means "comprising" or "consisting of". The skilled

artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that "having" means "comprising".

Claim 19 is rendered indefinite for improper antecedent usage as follows.

For Claim 19, the phrase "A nucleic acid molecule according to claim 1" should be corrected to "The nucleic acid molecule according to claim 1".

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 1, 3, 4, 5, 9, and 10 under 35 U.S.C. 112, first paragraph/enablement, for essentially the same reasons explained in the prior action, is maintained. Claim 20 is herein rejected under 35 U.S.C. 112, first paragraph/enablement, for the same reasons. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) Methods for generating variants of a parent polynucleotides, for example the genus of polynucleotides having at least 80% homology to SEQ ID NO: 1, are well-known in the art. This genus of polynucleotides then could be routinely tested with regard to encoding proteins having the ability to bind to protein kinase A regulatory subunit II using, for example, FRET-based assays.

(B) A recent precedential opinion, Ex parte Kubin, as been issued. Therein, the Board of Patent Appeals and Interferences found that it would not be an undue experimentation for the

skilled artisan to make and test the genus of proteins having at least 80% homology to the recited parent sequence. That case supports the enablement of the instant amended claims.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: As explained in the prior action, it is acknowledged that recombinant methods for making variants of a parent protein are known in the art. It is also acknowledged that methods for testing binding to protein kinase A regulator subunit II are known. However, Claims 1, 3, 4, 5, 9, and 10 do not recite the functional limitation of binding to protein kinase A regulatory subunit II. Said claims encompass proteins variants having any known or unknown functional characteristic(s) of the AKAP18δ of SEQ ID NO: 2. In addition, Claims 1, 3, 4, 5, 9, 10, and 20 fail to recite any structural limitation for the genus of proteins encoded by the recited polynucleotides. Thus, Claims 1, 3, 4, 5, 9, and 10 recite no structural or functional limitations, while Claim 20 recites no structural limitations for the proteins encoded by the recited nucleic acid molecules and encompasses an undefined genus of functional limitations. The polynucleotide of SEQ ID NO: 1 consists of 1062 nucleotides. The genus of variants having at least 80% identity to SEQ ID NO: 1 can be represented by the formula:

$$(3_1 + 3_2 + 3_3 + \ldots 3_{1062})^{20} \simeq 3 \times 10^{23} \text{ variants}$$

To make said genus of variants and test the encoded polypeptides for any known or unknown functional characteristic(s) of the AKAP18δ of SEQ ID NO: 2, even using high throughput methods, clearly represents undue experimentation.

(B) Reply: Ex parte Kubin is not analogous to the instant application for the following reasons. Referring to points 19-30 on pages 12-14 of Kubin:

19. The structural and functional limitations for the instant claims are extremely broad, compared to the claim of Kubin. Claim 73 in Kubin is limited to a genus of polypeptides that bind CD48 and have at least 80% identity to a parent protein of 200 amino acids. The instant claims are directed to a genus of polynucleotides having at least 80% identity to a parent nucleic acid molecule of 1062 nucleotides, wherein the polynucleotides encode a genus of proteins having any known or unknown activity of the AKAP18δ of SEQ ID NO: 2. Thus, the structural and functional limitations for the instant claims are extremely broad, compared to the claim of Kubin.

20-21. Kubin teaches several working examples having the desired activity. The instant application provides only one working example, SEQ ID NO: 2, of a protein having an activity of binding to protein kinase A regulator subunit II. In addition, the instant application provides provides no working examples for proteins having any other known or unknown activity of the AKAP18δ of SEQ ID NO: 2.

22-23. Neither Kubin nor the instant application teach which residues may or may not be altered and retain the desired biological function(s) for the encompassed proteins.

24. Both Kubin and the instant application teach how to make variant polynucleotides and proteins. Kubin teaches how to screen their variants for the desired activity. The instant application does not teach how to the screen the encoded variant proteins for all desired activities.

25. Neither Kubin nor the instant application teach a correlation between function and structure responsible for the desired activities.

26. Molecular biology is generally an unpredictable art.

27. The level of skill is high.

28. Methods for making variant polynucleotides and proteins were known.

29. As explained in (19), above the number of variants encompassed by the instant claims far surpasses the number of variants recited by Kubin. Moreover, testing all variants of the instant claims for the known and unknown desired activities represents undue experimentation because neither all desired activities nor methods for screening all desired activities are disclosed.

30. Thus, the amount of experimentation needed to practice the full scope of the recited invention is undue.

For these reasons and those explained in the prior action, 1, 3, 4, 5, 9, 10, and 20 are rejected under 35 U.S.C. 112, first paragraph/enablement.

Written Description

Rejection of Claims 1, 3, 4, 5, 9, and 10 under 35 U.S.C. 112, first paragraph/written description, for essentially the same reasons explained in the prior action, is maintained. Claim 20 is herein rejected under 35 U.S.C. 112, first paragraph/ written description, for the same reasons. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(C) The Claims have been amended in accordance with the USPTO's new Written Description Guidelines; see Example 11B of the Training Materials of 2008. The exemplary claims in said example are:

> Claim 1. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2.
>
> Claim 2. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2; wherein the polypeptide has activity Y.

The guidelines state that both of the above claims satisfy the requirement under 35 USC 112, first paragraph. With respect to claim 2, it is stated that "[although] the specification fails to teach which of the nucleic acid sequences that encode a polypeptide with at least 85% sequence identity to SEQ ID NO: 2 encode a polypeptide having the required activity Y .... the specification identifies domains responsible for activity Y." The guidelines further state that "Although conservative amino acid substitutions in these domains will not necessarily result in a protein having activity Y, those of ordinary skill in the art would expect that many of these conservative substitutions would result in a protein having the required activity".

This conforms to Applicants' present invention wherein the claimed AKAP8 polynucleotide of SEQ ID NO: 1 encodes a protein of SEQ ID NO: 2 which has a novel activity (for example, AKAP8 protein anchors protein kinase A (PKA) with Ca2+ channels or receptors in cells, as recited in present claim 20).

This argument is not found to be persuasive for the following reasons.

(C) Reply: First, the instant specification fails to disclose all desired biological functions for the encompassed variants of SEQ ID NO: 1, or the encoded proteins. Second, the instant specification fails to teach which domains, motifs, or amino acid residues of SEQ ID NO: 2 may or may not be altered and still retain the desired activities. Therefore, Applicants' present invention does not conform to Example 11B of the Training Materials of 2008 for the USPTO's new Written Description Guidelines.

For these reasons and those explained in the prior action, 1, 3, 4, 5, 9, 10, and 20 are rejected under 35 U.S.C. 112, first paragraph/written description.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection based or amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652